

## General

### Guideline Title

Evidence-based guideline: management of an unprovoked first seizure in adults: report of the Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society.

### Bibliographic Source(s)

Krumholz A, Wiebe S, Gronseth GS, Gloss DS, Sanchez AM, Kabir AA, Liferidge AT, Martello JP, Kanner AM, Shinnar S, Hopp JL, French JA. Evidence-based guideline: management of an unprovoked first seizure in adults: report of the Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2015 Apr 21;84(16):1705-13. [38 references]  
[PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Recommendations

### Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (Class I-IV) are provided at the end of the "Major Recommendations" field.

#### Recommendations

- Adults presenting with an unprovoked first seizure should be informed that the chance for a recurrent seizure is greatest within the first 2 years after a first seizure (21% to 45%) (Level A).
- Clinicians should also advise such patients that clinical factors associated with an increased risk of seizure recurrence include a prior brain insult such as a stroke or trauma (Level A), an electroencephalogram (EEG) with epileptiform abnormalities (Level A), a significant brain-imaging abnormality (Level B), or a nocturnal seizure (Level B).
- Clinicians should advise patients that, although immediate antiepileptic drug (AED) therapy, as compared with delay of treatment pending a second seizure, is likely to reduce the risk of a seizure recurrence in the 2 years subsequent to a first seizure (Level B), it may not improve quality of life (QOL) (Level C).
- Clinicians should advise patients that over the longer term (>3 years), immediate AED treatment is unlikely to improve the prognosis for sustained seizure remission (Level B).
- Patients should be advised that their risk for AED adverse events (AEs) ranges from 7% to 31% (Level B) and that these AEs are predominantly mild and reversible.

## Clinical Context

For an adult with a first seizure, the risk of a recurrence poses major concerns and raises the question of whether immediate AED treatment is advisable. It is a proposed and now generally accepted principle that when a patient with a first seizure has one or more ensuing seizures, an AED should be initiated because the risk of yet additional seizures is very high (57% by 1 year and 73% by 4 years), with risk increasing proportionally after each subsequent recurrence as the time interval between seizures decreases. In contrast, immediate AED treatment at the time of the first unprovoked seizure is not well accepted and is debated.

For a patient with a first unprovoked seizure, the chance for a seizure recurrence can be estimated and stratified on the basis of clinical factors, with greater risk associated with a prior brain insult or lesion as the cause of the seizure, an EEG with epileptiform abnormalities, a significant brain-imaging abnormality, or a nocturnal seizure. Such risk stratification may help guide physicians counseling patients about their risks for seizure recurrence and options for management. In some instances, a patient's statistical risk for a seizure recurrence may approach that of patients for whom immediate AED treatment is generally accepted, such as those who have already experienced multiple seizures. A recent report from the International League Against Epilepsy (ILAE) promotes a new practical clinical definition of epilepsy that emphasizes the importance of estimating recurrence risk for individuals with a first unprovoked seizure. The ILAE expanded the diagnosis of epilepsy beyond the prior standard requiring at least 2 unprovoked seizures to encompass people with an unprovoked seizure and a high (at least 60%) risk of seizure recurrence over the subsequent 10 years. However, as analysis indicates and the ILAE cautions, the lack of evidence regarding specific risk factors and their interactions poses limitations.

Some of these risk factors may be independent predictors for risk of recurrence, whereas others (e.g., a prior brain lesion as a seizure cause, or a brain-imaging abnormality) likely are related. The relatively small numbers of subjects in studies addressing this issue limit the strength of evidence. Only 2 studies analyzed evidence specifically regarding additive effects or covariance of the risk factors for seizure recurrence after a first seizure, and reached somewhat different conclusions. One study noted that the only independent risk factor for seizure recurrence was an EEG with epileptiform abnormalities, and the other reported a remote symptomatic seizure etiology as the only independent risk factor. Because of this lack of evidence, caution is urged regarding the calculation of additive risk of seizure recurrence after a first unprovoked seizure. The ILAE report states as much: "No formula can be applied for additive risks since data are lacking on how such risks combine; such risks will have to be decided by individualized considerations." Such caution also applies to decisions in AED treatment.

Indications for immediate AED treatment are based largely but not only on estimations of an individual's risk of a seizure recurrence. Physicians planning to prescribe an AED for treatment should also carefully consider the drug's specific therapeutic and AE profiles on an individualized basis. Evidence indicates that immediate AED therapy is likely to reduce seizure recurrence risk for individuals with an unprovoked first seizure, particularly within the first 2 years. Such seizure recurrence prevention, even in the short term, may be important, with potentially greater implications for adults than for children. For adults, seizure recurrences may cause such serious psychological and social consequences as loss of driving privileges and limitations on employment. Still, one controlled Class II study comparing immediate AED treatment with treatment deferred until after a seizure recurrence found no significant difference in standard 2-year QOL measures. However, that study also noted that patients who were not immediately treated with AEDs were more likely to be restricted from driving.

The longer-term prognosis for patients with a first seizure as measured by whether patients maintain seizure freedom demonstrates no benefit for immediate AED treatment. Moreover, although individual seizure recurrences pose some risk for physical harm and even death, there is no evidence that immediate AED treatment reduces that risk or improves QOL. Also, the only study appraising the incidence of sudden unexplained death after an unprovoked first seizure demonstrates no advantage with immediate AED therapy.

## Definitions:

### Classification of Evidence Schemes

#### Classification of Therapeutic Evidence

Class I. Randomized controlled clinical trial (RCT) in a representative population. Masked or objective outcome assessment. Relevant baseline characteristics are presented and substantially equivalent between treatment groups, or there is appropriate statistical adjustment for differences. Also required: Concealed allocation. Primary outcomes clearly defined. Exclusion/inclusion criteria clearly defined. Adequate accounting for dropouts.

Class II. Cohort study meeting criteria for Class I or a RCT that lacks one or two of those other criteria. All relevant baseline characteristics are present and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences. Masked or objective outcome assessment.

Class III. Controlled studies (including well-defined natural history controls or patients serving as their own controls). A description of major

confounding differences between treatment groups that could affect outcome. Outcome assessment masked, objective or performed by someone who is not a member of the treatment team.

Class IV. Did not include patients with the disease. Did not include patients receiving different interventions. Undefined or unaccepted interventions or outcome measures. No measures of effectiveness or statistical precision present or calculable.

#### Classification of Prognostic Evidence

Class I. Cohort survey with prospective data collection. Includes a spectrum of persons at risk for developing the outcome. Outcome measurement is objective or determined without knowledge of risk for developing the outcome. Also required: a. Inclusion criteria defined b. At least 80% of enrolled subjects have both the risk factor and outcome measured.

Class II. Cohort study with retrospective data collection or case-controlled study. Study meets criteria a and b (see Class I). Includes a broad spectrum of persons with and without the risk factor and the outcome. The presence of the risk factor and outcome are determined objectively or without knowledge of one another.

Class III. Cohort or case control study. Narrow spectrum of persons with or without the disease. The presence of the risk factor and outcome are determined objectively or without knowledge of the other or by different investigators.

Class IV. Did not include patients at risk for the outcome. Did not include patients with and without the risk factor. Undefined or accepted measures of risk factor or outcomes. No measures of association or statistical precision presented or calculable.

#### Classification of Recommendations

Level A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)\*

Level B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

\*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Unprovoked first seizure

### Guideline Category

Management

Risk Assessment

Treatment

# Clinical Specialty

Neurology

## Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To provide evidence-based recommendations for treatment of adults with an unprovoked first seizure

## Target Population

Adults with or suspected of having an unprovoked first seizure

## Interventions and Practices Considered

1. Informing patients about the chance for a recurrent seizure within the first two years after an unprovoked first seizure and clinical risk factors for seizure recurrence
2. Advising patients about benefits and risks of immediate antiepileptic drug (AED) therapy versus delayed treatment
3. Advising patients that AED therapy will likely reduce seizure reoccurrence risk but not improve long-term prognosis for seizure remission

## Major Outcomes Considered

- Risk of/rate of seizure recurrence (short-term and long-term)
- Quality of life (QOL)
- Adverse events (AEs) associated with antiepileptic drug (AED) therapy

## Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

The Committee searched MEDLINE, EMBASE, and Cochrane Central Register of Controlled Trials databases (1966 to March 2013), and reviewed the literature for relevant publications using established criteria. See Appendix e-3 of the data supplement (see the "Availability of Companion Documents" field) for complete search strategies for each of the databases.

They identified 2,613 articles, obtained all in abstract form, and selected 281 for full-text review.

Exclusion Criteria

Exclusion criteria comprise the following:

- Letters and case reports
- Non-English-language studies
- Animal studies
- Pharmacodynamic/pharmacokinetic studies
- Studies dealing primarily with patients with established or chronic epilepsy
- Studies dealing primarily with acute provoked seizures

#### Inclusion Criteria

- Study designs: observational (prospective, retrospective, and cross-sectional), or interventional (randomized, controlled trials [RCTs], nonrandomized, controlled trials [nRCTs], and uncontrolled case series [UCS])
- At least 10 patients, adults, with a first seizure, a first presentation with epilepsy or seizures, or a first diagnosis of epilepsy
- Patients should be over the age of 18 or the study should include a substantial proportion of subjects over the age of 18
- Studies reported in English only
- Studies dealing primarily with apparent unprovoked first seizures

## Number of Source Documents

47 articles were judged relevant and acceptable

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

### Classification of Evidence Schemes

#### Classification of Therapeutic Evidence

Class I. Randomized controlled clinical trial (RCT) in a representative population. Masked or objective outcome assessment. Relevant baseline characteristics are presented and substantially equivalent between treatment groups, or there is appropriate statistical adjustment for differences. Also required: Concealed allocation. Primary outcomes clearly defined. Exclusion/inclusion criteria clearly defined. Adequate accounting for dropouts.

Class II. Cohort study meeting criteria for Class I or a RCT that lacks one or two of those other criteria. All relevant baseline characteristics are present and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences. Masked or objective outcome assessment.

Class III. Controlled studies (including well-defined natural history controls or patients serving as their own controls). A description of major confounding differences between treatment groups that could affect outcome. Outcome assessment masked, objective or performed by someone who is not a member of the treatment team.

Class IV. Did not include patients with the disease. Did not include patients receiving different interventions. Undefined or unaccepted interventions or outcome measures. No measures of effectiveness or statistical precision present or calculable.

#### Classification of Prognostic Evidence

Class I. Cohort survey with prospective data collection. Includes a spectrum of persons at risk for developing the outcome. Outcome measurement is objective or determined without knowledge of risk for developing the outcome. Also required: a. Inclusion criteria defined b. At least 80% of enrolled subjects have both the risk factor and outcome measured.

Class II. Cohort study with retrospective data collection or case-controlled study. Study meets criteria a and b (see Class I). Includes a broad spectrum of persons with and without the risk factor and the outcome. The presence of the risk factor and outcome are determined objectively or

without knowledge of one another.

Class III. Cohort or case control study. Narrow spectrum of persons with or without the disease. The presence of the risk factor and outcome are determined objectively or without knowledge of the other or by different investigators.

Class IV. Did not include patients at risk for the outcome. Did not include patients with and without the risk factor. Undefined or accepted measures of risk factor or outcomes. No measures of association or statistical precision presented or calculable.

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

The authors systematically reviewed and rated the 47 articles according to the American Academy of Neurology (AAN) classification of evidence scheme for prognostic or therapeutic articles (see the "Rating Scheme for the Strength of the Evidence" field).

Appendix e-7 of the data supplement (see the "Availability of Companion Documents" field) presents all rated articles. Tables e-1 through e-4 of the data supplement show the data.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

This guideline is an evidence-based appraisal from a systematic review of the literature published in English and based on established 2004 process standards from the American Academy of Neurology (AAN) Guideline Development Subcommittee (see Appendices e-1 and e-2 of the data supplement [see the "Availability of Companion Documents" field]).

This practice guideline considers the evidence for prognosis and treatment of adults with an unprovoked first seizure. The authors posed three questions:

1. What are the risks for seizure recurrence after a first seizure?
2. Does immediate treatment with an antiepileptic drug (AED) reduce or change (a) short-term risks for a seizure recurrence or (b) long-term prognosis for seizure freedom or remission?
3. For those patients prescribed AEDs immediately, what are the risks for adverse events (AEs)?

The recommendations were linked to evidence strength based primarily on studies rated Class I or II (see the "Rating Scheme for the Strength of the Recommendations" field).

## Rating Scheme for the Strength of the Recommendations

### Classification of Recommendations

Level A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)\*

Level B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

\*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Drafts of the guideline have been reviewed by at least 3 American Academy of Neurology (AAN) committees, at least one American Epilepsy Society (AES) committee, a network of neurologists, Neurology peer reviewers, and representatives from related fields.

The guideline was approved by the Guideline Development Subcommittee on November 16, 2013; by the Practice Committee on January 20, 2014; by the AES Board of Directors on February 13, 2014; and by the American Academy of Neurology Institute (AANI) Board of Directors on December 1, 2014.

This guideline was endorsed by the World Federation of Neurology on May 20, 2014, and by the American Neurological Association on May 21, 2014.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate management of an unprovoked first seizure in adults

### Potential Harms

Patients should be advised that risk of antiepileptic drug (AED) adverse events (AEs) may range from 7% to 31% and that these AEs are likely predominantly mild and reversible.

## Qualifying Statements

### Qualifying Statements

Clinical practice guidelines, practice advisories, systematic reviews, and other guidance published by the American Academy of Neurology (AAN) and its affiliates are assessments of current scientific and clinical information provided as an educational service. The information: (1) should not be

considered inclusive of all proper treatments, methods of care, or as a statement of the standard of care; (2) is not continually updated and may not reflect the most recent evidence (new evidence may emerge between the time information is developed and when it is published or read); (3) addresses only the question(s) specifically identified; (4) does not mandate any particular course of medical care; and (5) is not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. AAN provides this information on an "as is" basis, and makes no warranty, expressed or implied, regarding the information. AAN specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. AAN assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information or for any errors or omissions.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

Staying Healthy

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

Krumholz A, Wiebe S, Gronseth GS, Gloss DS, Sanchez AM, Kabir AA, Liferidge AT, Martello JP, Kanner AM, Shinnar S, Hopp JL, French JA. Evidence-based guideline: management of an unprovoked first seizure in adults: report of the Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2015 Apr 21;84(16):1705-13. [38 references]



## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2015 Apr 21

## Guideline Developer(s)

American Academy of Neurology - Medical Specialty Society

American Epilepsy Society - Disease Specific Society

## Source(s) of Funding

This guideline was developed with financial support from the American Academy of Neurology.

## Guideline Committee

Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society

## Composition of Group That Authored the Guideline

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## Financial Disclosures/Conflicts of Interest

### Conflict of Interest

The American Academy of Neurology (AAN) and the American Epilepsy Society (AES) are committed to producing independent, critical, and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN and AES keep separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee before project initiation. AAN and AES limit the participation of authors with substantial conflicts of interest. The AAN and AES forbid commercial participation in, or funding of, guideline projects. Drafts of the guideline have been reviewed by at least 3 AAN committees, at least one AES committee, a network of neurologists, Neurology peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at [www.aan.com](http://www.aan.com) . For complete information on this process, access the 2004 AAN process manual.

### Disclosures

A. Krumholz serves on the editorial board for *Clinical EEG and Neuroscience*, and has received royalties from UpToDate.

S. Wiebe has received research funding from the Alberta Heritage Medical Research Foundation, the Canadian Institutes for Health Research, the M.S.I. Foundation of Alberta, and the Hotchkiss Brain Institute of the University of Calgary.

G. Gronseth reports no disclosures relevant to the manuscript.

D. Gloss is a paid evidence-based medicine consultant for the American Academy of Neurology.

A. Sanchez, A. Kabir, A. Lifèridge, and J. Martello report no disclosures relevant to the manuscript.

A. Kanner serves as a journal editor for *Epilepsy Currents* and as a regional editor for *Epileptology*; serves on the editorial boards of *Epilepsy & Behavior* and *CNS Spectrums*; and has received royalties for *Psychiatric Issues in Epilepsy, Second Edition: A Practical Guide to Diagnosis and Treatment*; *Psychiatric Controversies in Epilepsy*; and *Depression in Neurologic Disorders*.

S. Shinnar has served on scientific advisory boards for Acorda, Questcor, and Upsher-Smith; has received royalties for *Febrile Seizures* and honoraria from Questcor, UCB, and Upsher-Smith; has received research funding from the National Institute of Neurological Disorders and Stroke and the Citizens United for Research in Epilepsy Foundation; and has given expert testimony.

J. Hopp has received royalties from publishing from UpToDate and honoraria from lectures for UCB Pharma, has served on speakers bureaus for UCB Pharma and GlaxoSmithKline, and has given expert testimony.

J. French has served as a consultant for Acorda, Biotie, Eisai Medical Research, GlaxoSmithKline, Impax, Johnson & Johnson, LCGH, Marinus, Novartis, Pfizer, Sunovion, SK Life Science, Supernus Pharmaceuticals, UCB, Upsher-Smith, and Vertex; has received grants from Eisai Medical Research, Epilepsy Research Foundation, Epilepsy Study Consortium, Epilepsy Therapy Project, Lundbeck, Pfizer, and UCB; and is president of the Epilepsy Study Consortium. All consulting is done on behalf of the Consortium, and fees are paid to the Consortium. New York University receives salary support from the Consortium.

Go to [Neurology.org](https://www.neurology.org)  for full disclosures.

## Guideline Endorser(s)

American Neurological Association - Professional Association

World Federation of Neurology - Medical Specialty Society

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to this guideline, is available from the [AAN Web site](#) .

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 201 Chicago Avenue South, Minneapolis, MN 55415.

## Availability of Companion Documents

The following are available:

- Evidence-based guideline: management of an unprovoked first seizure in adults: report of the Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Data supplement (e-appendices, e-tables). St. Paul (MN): American

Academy of Neurology; 2015. Electronic copies: Available from the [Neurology Journal Web site](#) .

- Evidence-based guideline: management of an unprovoked first seizure in adults: report of the Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Slide presentation. St. Paul (MN): American Academy of Neurology; 2015. Electronic copies: Available from the [American Academy of Neurology \(AAN\) Web site](#) .
- Evidence-based guideline: management of an unprovoked first seizure in adults: report of the Guideline Development Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Summary of evidence-based guideline for clinicians. St. Paul (MN): American Academy of Neurology. 2015; 2 p. Electronic copies: Available from the [AAN Web site](#) .
- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Electronic copies: Available from the [AAN Web site](#) .

## Patient Resources

The following is available:

- Managing an unprovoked first seizure in adults. Summary of evidence-based guideline for patients and their families. St. Paul (MN): American Academy of Neurology; 2015. 2 p. Electronic copies: Available from the [American Academy of Neurology \(AAN\) Web site](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

## NGC Status

This NGC summary was completed by ECRI Institute on May 19, 2015. The information was not verified by the guideline developer.

## Copyright Statement

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## Disclaimer

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